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APPLICATION NO.	. FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/521,230	01/13/2005	Songqing Na	X-15815	5443	
	25885 7590 03/09/2007 ELI LILLY & COMPANY			EXAMINER	
PATENT DIVISION P.O. BOX 6288 INDIANAPOLIS, IN 46206-6288			JIANG, DONG		
			ART UNIT	PAPER NUMBER	
•	,		1646		
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE		
31 D	AYS	03/09/2007	ELECTRONIC		

## Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 31 DAYS from 03/09/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

	Application No.	Applicant(s)					
Office A. C O	10/521,230	NA ET AL.					
Office Action Summary	Examiner	Art Unit					
	Dong Jiang	1646	_				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status .							
1) Responsive to communication(s) filed on 13 Ja	nuary 2005						
· · · · · · · · · · · · · · · · · · ·	action is non-final.						
·							
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-19 and 22</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
7) Claim(s) is/are objected to.	· ·						
8) Claim(s) 1-19 and 22 are subject to restriction a	and/or election requirement						
	andror election requirement.						
Application Papers							
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.					
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
		•					
Attachment(s)							
Notice of References Cited (PTO-892)	4) Interview Summary	(PTO-413)					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	Paper No(s)/Mail Date					
B) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application  6) Other:							
	-/ L.J						

Art Unit: 1646

## **DETAILED ACTION**

Applicant's preliminary amendment filed on 13 January 2005 is acknowledged and entered. Following the amendment, the original claims 20 and 21 are canceled, claim 4 is amended, and the new claim 22 is added.

Currently, claims 1-19 and 22 are pending.

## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7 and 17 in part, drawn to an isolated nucleic acid, a composition thereof, a vector comprising the nucleic acid, a host cell thereof, and a recombinant process for producing the encoded polypeptide.

Group II, claim(s) 8-13, and 17 in part, drawn to an isolated polypeptide, a chimeric molecule thereof, and a composition thereof.

Group III, claim(s) 14-16, 17 in part, and 22, drawn to an isolated antibody, and a composition thereof.

Group IV, claim(s) 17 in part, drawn to an agonist of the polypeptide.

Group V, claim(s) 17 in part, drawn to an antagonist of the polypeptide.

Group VI, claim(s) 17 in part, drawn to an anti-LP polypeptide-encoding mRNA specific ribozyme.

Group VII, claim(s) 18, drawn to a method of treatment with the polypeptide.

Group VIII, claim(s) 19, drawn to a method of diagnosis.

Application/Control Number: 10/521,230

Art Unit: 1646

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Page 3

Pursuant to 37 C.F.R., the main invention in the instant application comprises the firstrecited product, an isolated nucleic acid, a variant and a fragment thereof, and the first-recited method of using that product, namely a process of recombinant production of the encoded polypeptide. Note that there is no method of making the nucleic acid. Also included in this group are a composition of the nucleic acid, and an expression vector and a host cell containing the nucleic acid. Although the polypeptide of Group II is encoded by the nucleic acid of Group I, neither the nucleic acid nor the polypeptide encoded thereby is an advance over the prior art. For example, it is apparent that Chen et al. (US6,569,645) discloses a nucleic acid, SEQ ID NO:11, which encodes a polypeptide (SEQ ID NO:12) with 96.8% sequence identity to the present SEQ ID NO:2 (See appended computer printout of sequence search results). The Chen reference renders claim 1, among the other, not novel. Thus the technical feature of the nucleic acid is not special and the groups are not so linked under PCT Rule 13.1. Additionally, the other claimed products in groups III-VI are physically and functionally distinct chemical entities, which share neither structure nor function with that of Group I, and therefore, are not so linked to the main invention by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single general inventive concept. The additional methods of groups VII and VIII do not correspond to the main invention, as they are neither a method of making, nor a method of using said nucleic acid. Therefore, they are not considered to share a special technical feature with the main invention within the meaning of PCT Rule 13.2, and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1.

- 2. Furthermore, regardless of which Invention applicants elect above, further restriction is required under 35 U.S.C. 121 and 372:
- A. One specific nucleic acid sequence with SEQ ID NO:, i.e. SEQ ID NO:1, 3, 5, 7, 9, 11, 13, 15, 17, 19, 21 or 23.

Application/Control Number: 10/521,230

Art Unit: 1646

The nucleic acids having different SEQ ID NO as listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each of SEQ ID NOs represents a unique and structurally distinct chemical entity, and the SEQ ID NOs are unrelated, each to each other. Therefore, they do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single invention concept within the meaning of PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-VIII, and an election of the invention from Group A, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-VIII nor A is species election requirement; rather, each of I-VIII and A is a restriction requirement.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1646

## Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on 9:30 am - 7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dong Jiang, Ph.I. Patent Examiner

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